



OFFICE OF THE VICE PROVOST

Social, Behavioral, and Educational Research
Institutional Review Board

Re: IRB Study # 11602L*1
Title: 4-H Study of Positive Youth Development
PI: Richard Lerner
IRB Review Date: 2/20/2009

February 23, 2009

Dear Richard,

The Institutional Review Board (IRB) has reviewed the request for protocol modification dated 2/18/2009 to the above referenced study.

This amended protocol meets the requirements set forth by the IRB and is hereby approved. Approval is valid for a period of one year from the original IRB Review Date and expires on 7/14/2009.

Approved changes to the consent form are detailed below:

- 1) Modification to consent administered to participants in North Carolina allowing them the opportunity to access study data for that state.
- 2) Removal of parental consent from the North Carolina consent form to be administered to participants 18 years of age and older.

Enclosed you will find stamped consent forms and other study materials that show the date through which these materials are valid. Only copies of these stamped consent forms and materials may be utilized for conducting your study.

Any changes to the protocol, consent forms or study materials must be submitted to the Office of the IRB for approval by completing the *Request for Protocol Modification* form. In addition, all Adverse Events and Unanticipated Problems must be reported to the Office of the IRB promptly, and by utilizing the appropriate reporting forms.

Investigators are required to submit a *Request for Continuing Review* or a *Request for Study Closure* six weeks prior to the expiration date of the protocol.

Please know that the PI is responsible for all information contained in both this letter and on the Investigator Responsibilities Sheet. If anything is unclear or if you have any questions, please contact the IRB office at (617) 627-3417.

Sincerely,

A handwritten signature in black ink, appearing to read "Yvonne Wakeford".

Yvonne Wakeford, Ph.D.
IRB Administrator

IN THE KNOW

BULLETIN OF THE TUFTS SBER IRB MEDFORD CAMPUS

ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

Did you know that Adverse Events and Unanticipated Problems must be reported to the IRB office within seven days of the occurrence?

Please use the *Adverse Event Reporting* form or the *Unanticipated Problem Reporting* form that can be found on the website at:
<http://www.tufts.edu/central/research/IRB/index.htm>

ADVERSE EVENTS

- Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (can be both physical and/or psychological).
- Example: A participant becomes upset by fear provoking stimuli, even though this was anticipated and mentioned in the consent form.

UNANTICIPATED PROBLEMS

- Include any incident, experience, or outcome that meets **all** of the following criteria:
 1. Unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents and the characteristics of the subject population being studied *and*
 2. Related or *possibly related* to participation in the research (there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research) *and*
 3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.
- Example: Participants become upset by stimuli, but this was not expected.



OFFICE OF THE VICE PROVOST

Social, Behavioral, and Educational Research
Institutional Review Board

INVESTIGATOR RESPONSIBILITIES

Investigators who are conducting research using human participants have the following responsibilities:

- To comply with the Code of Federal Regulations regarding the protection of human subjects.
 - <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- To protect the rights and welfare of all human subjects.
- To ensure that each potential participant understands the nature of the research.
- To ensure that the correct procedures are followed to gain *informed* consent from each person prior to participation.
- To provide each participant with a copy of the IRB approved consent document unless waived by the IRB.
- To ensure that all researchers, research assistants and faculty advisors have completed the required CITI training and that the certification is current. Certification is valid for a period of 5 years.
- To conduct all research according the Institutional Review Board (IRB) approved protocol.
- To not initiate any changes to the protocol without IRB review and approval, unless it is necessary to eliminate an immediate hazard.
 - Submit the *Request for Protocol Modification* form.
- To submit to the IRB for continuing review at least 6 weeks prior to the expiration date of the protocol if the research is going to continue past the expiration date.
 - Submit the *Request for Continuing Review* form.
- To officially close the study once completed.
 - Submit the *Request for Study Closure* form.
- To promptly report any unanticipated problems to the IRB.
 - Submit the *Unanticipated Problem Report* form.
- To promptly report any adverse events to the IRB.
 - Submit the *Adverse Event Report* form.
- To retain all data and signed consent documents for at least 3 years beyond the completion of the research.

Please refer to the website for additional information:

<http://www.tufts.edu/central/research/IRB/main.htm>

Feel free to contact us if you need any assistance.

Revised 1/23/2008

North Carolina State University
INFORMED CONSENT FORM for RESEARCH

Title of Study: 4-H Positive Youth Development

Principal Investigator: Benjamin Silliman, Ph.D., Department of 4-H Youth Development & Family and Consumer Sciences

In collaboration with: Richard M. Lerner, Ph.D. Principal Investigator for the 4-H National study of Positive Youth Development,
& Jacqueline V. Lerner, Ph.D., Scientific Director, Eliot-Pearson Department of Child Development, Tufts University

PURPOSE OF STUDY

You are invited to participate in a study of the positive development of children in America. Our goal is to learn more about the kind of experiences that help children develop into healthy, productive adults.

DATA TO BE COLLECTED

If he/she agrees to participate in this study, you/your child will be asked to complete a survey that takes approximately 90 minutes. Administration of the survey will be done one time per year, for the duration of the study, and will be done at your child's school, after school program, or youth organization. Questions on the survey will ask children to tell us about their relationship with their family and friends, and activities in which they are involved at school and after school. Children will also be asked about their physical development, feelings about themselves, and future goals and expectations. Some of the questions deal with personal topics such as health and sexual behaviors, smoking and drug use.

RISKS

Some of the survey questions may make you or your child uncomfortable. Although we would like you and your child to answer all the questions, you and your child are free to skip any question that either of you do not wish to answer. Another risk is from accidental breach of confidentiality. In order to prevent this, we are taking steps to protect your confidentiality by using a code number to link your identity and your responses, so that your names is not directly associated with your responses.

BENEFITS

Responses provided by you and your child will help us learn more about the experiences that promote children's positive development. This kind of information is needed to create effective programs for children and national and local policies that are beneficial to children and families. Additional and immediate benefits include 1) You may find it interesting or helpful to express your experiences and opinions; 2) After completing the survey, your child will be entered into a raffle to win a prize; 3) Findings from this study, which **will not include** individual details about you, will be made available to you and your school or program. **Upon request, a summary of the North Carolina data will be provided to you.**

CONFIDENTIALITY

Your and your child's identity and information will be kept confidential, except as required by law. No names will be placed on surveys and completed surveys will be kept at Tufts University, separate from records of participation. Only members of the research team will have access to the surveys, and all information will be used for research purposes only. We only will use your address and telephone number, if you wish to provide it, to send thank-you cards and additional correspondence.

COMPENSATION

After completing the survey, your child will be entered into a raffle to win a prize. Students who withdraw from the study prior to its completion will not be eligible for the drawing.

EMERGENCY MEDICAL TREATMENT

Youth will be completing the survey at a desk or work station, so emergency medical treatment is not likely to be needed. Data collectors will contact professional assistance (911) if an emergency should occur.

CONTACT

If you have questions at any time about the study or the procedures, you may contact Dr. Ben Silliman at 512 Brickhaven Road, NCSU or (919) 515-8485. If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact Deb Paxton, Regulatory Compliance Administrator, Box 7514, NCSU Campus (919/515-5414) or Joe Rabiega, IRB Coordinator, Box 7514, NCSU Campus (919/515-7515).

PARTICIPATION. Your participation in this study is voluntary; you may decline to participate without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed, your data will be destroyed. You may be contacted annually and asked to continue your participation.

CONSENT PROCEDURE

If you agree to participate, please do the following:

- 1) Read this Consent Form (**Pages 1 & 2**) and indicate whether or not you agree to your participation and your child's participation on the Signature Form (**Page 3**).
- 2) Detach the Signature Form (**Page 3**) and have your child return it to his or her school, after school program, or youth organization. Keep the Consent Form (**Pages 1 & 2**) for your records.
- 3) Complete the online Parent Survey (it only takes about 20 minutes) using the Parent Online login information provided. You can also call us to request a paper copy (please see following page for contact information).

APPROVED

FEB 20 2009

Tufts SBEB IRB

EXPIRES

JUL 14 2009

Tufts SBEB IRB

4-H Study of Positive Youth Development

PARENT CONSENT STATEMENT

I understand that participation in this study is voluntary. I understand that my child and I may refuse to participate in this study. I also understand that if, for any reason, I/my child wishes to discontinue participation in this study at any time, I/my child will be free to do so, without any negative consequences. I have been fully informed of the above-described study with its risks and benefits, and I hereby consent that I and my child participate(s) in this research. I have received a signed copy of this consent form. I consent to participate in the described research. I, also, give permission for my child's current and subsequent participation in the study and for the information already collected about my child in the past to be used by the research team.

CHILD INFORMATION (Please read this to your child under 18 years)

Your parent has said that it is O.K. for you to participate in our study as long as it is O.K. with you. We are interested in finding out about the kind of things that are important to children. There will be questions about you, the kinds of things you do, your school, your health, your family, and your friends. Different kids have different experiences and opinions and we would like to hear about yours.

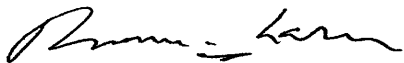
Please answer all of the questions honestly. If for any reason you do not wish to answer a question, you may skip it and go on to the next one. If you decide that you don't want to participate, you may tell us that you want to stop without any negative consequences from the researchers or from your school, after school program, or youth organization.

Your name will not be on any of the answer sheets, so no one will know how you answered the questions.

You will be given the survey in your school, after school program, or youth organization. It will take you about an hour and a half to complete the survey. You can take a break when you need one. You may also take some more time if you feel that you need it.

Researcher's Statement:

I have fully disclosed to Parent/Legal Guardian/Participant the nature and purpose of the research.



September 30, 2007

Signature of Principal Investigator, National Study

DATE



January 14, 2008

Signature of Principal Investigator, North Carolina Study

DATE

APPROVED

FEB 20 2009

Tufts SBER IRB

EXPIRES

JUL 14 2009

Tufts SBER IRB

SIGNATURE FORM

4-H Study of Positive Youth Development

☐ **Parent(s):** Please **ONLY** check this box if you **DO NOT CONSENT** to your child's participation in this study.

PARENT'S CONSENT:

I have read and understood the above information. I consent to participate in the described research and I give my consent for my child to participate.

Parent/Guardian's Signature

Date

Please PRINT **Your** Name

Your Child's Signature

Date

Please PRINT **Child's** Name

**PLEASE HAVE YOUR CHILD RETURN THIS PAGE TO HIS/HER
TEACHER OR PROGRAM LEADER!
(OR IF 18 OR OLDER, RETURN THIS FORM YOURSELF)**

(KEEP FIRST PAGE FOR YOUR RECORDS)

4-H Study of Positive Youth Development
Lincoln Filene Building,
Tufts University, Medford, MA 02155

APPROVED

FEB 20 2009

Tufts SBER IRB

EXPIRES

JUL 14 2009

Tufts SBER IRB

North Carolina State University
INFORMED CONSENT FORM for RESEARCH
(YOUTH, 18 Years and Over)

Title of Study: 4-H Positive Youth Development

Principal Investigator: Benjamin Silliman, Ph.D., Department of 4-H Youth Development & Family and Consumer Sciences

In collaboration with: Richard M. Lerner, Ph.D. Principal Investigator for the 4-H National study of Positive Youth Development,
& Jacqueline V. Lerner, Ph.D., Scientific Director, Eliot-Pearson Department of Child Development, Tufts University

PURPOSE OF STUDY

You are invited to participate in a study of the positive development of children in America. Our goal is to learn more about the kind of experiences that help children develop into healthy, productive adults. Your participation is requested because your adult child (over 18 years) is also participating in the study.

DATA TO BE COLLECTED

You will be asked to complete a survey that takes approximately 90 minutes. Administration of the survey will be done one time per year, for the duration of the study. An online survey will be sent to you if your child lists your e-mail address when he/she completes the survey. Questions on the survey will ask you to tell us about your child's relationships with your family and friends, and activities in which he/she is involved at school and after school. You will also be asked about their physical development, feelings themselves, and future goals and expectations. Some of the questions deal with personal topics such as health and sexual behaviors, smoking and drug use.

RISKS

Some of the survey questions may make you uncomfortable. Although we would like you to answer all the questions, you are free to skip any question that you do not wish to answer. Another risk is from accidental breach of confidentiality. In order to prevent this, we are taking steps to protect your confidentiality by using a code number to link your identity and your responses, so that your name is not directly associated with your responses.

BENEFITS

Responses provided by you will help us learn more about the experiences that promote children's positive development. This kind of information is needed to create effective programs for children and national and local policies that are beneficial to children and families. Additional and immediate benefits include 1) You may find it interesting or helpful to express your experiences and opinions; 2) After completing the survey, your child will be entered into a raffle to win a prize; 3) Findings from this study, which **will not include** individual details about you or your child, will be made available to you and your school or program. Upon request, a summary of the North Carolina data will be provided to you.

CONFIDENTIALITY

Your identity and information will be kept confidential, except as required by law. No names will be placed on surveys and completed surveys will be kept at Tufts University separate from records of participation. Only members of the research team will have access to the surveys, and all information will be used for research purposes only. We only will use your address and telephone number, if you wish to provide it, to send thank-you cards and additional correspondence.

COMPENSATION

After completing the survey, your child will be entered into a raffle to win a prize. Students who withdraw from the study prior to its completion will not be eligible for the drawing.

EMERGENCY MEDICAL TREATMENT

You will be completing the survey at a desk or work station, so emergency medical treatment is not likely to be needed. Data collectors will contact professional assistance (911) if an emergency should occur.

CONTACT

If you have questions at any time about the study or the procedures, you may contact Dr. Ben Silliman at 512 Brickhaven Road, NCSU or (919) 515-8485. If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact Deb Paxton, Regulatory Compliance Administrator, Box 7514, NCSU Campus (919/515-5414) or Joe Rabiega, IRB Coordinator, Box 7514, NCSU Campus (919/515-7515).

PARTICIPATION. Your participation in this study is voluntary; you may decline to participate without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed, your data will be destroyed. You may be contacted annually and asked to continue your participation.

CONSENT PROCEDURE

If you agree to participate, please do the following:

- 1) Read this Consent Form (**Pages 1 & 2**) and indicate whether or not you agree to your participation and your child's participation on the Signature Form (**Page 2**).
- 2) Detach the Signature Form (**Page 2**) and return it to his or her school, after school program, or youth organization. Keep the Consent Form (**Page 1**) for your records.

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FEB 20 2009

Tufts SBER IRB

EXPIRES

JUL 14 2009

Tufts SBER IRB


4-H Study of Positive Youth Development

CONSENT STATEMENT (for parents of youth 18 years and older)

I understand that participation in this study is voluntary. I understand that I may refuse to participate in this study. I also understand that if, for any reason, I wish to discontinue participation in this study at any time, I will be free to do so, without any negative consequences. I have been fully informed of the above-described study with its risks and benefits, and I hereby consent that I participate(s) in this research. I have received a signed copy of this consent form. I consent to participate in the described research.

Researcher's Statement:

I have fully disclosed to Parent/Legal Guardian/Participant the nature and purpose of the research.



September 30, 2007

Signature of Principal Investigator, National Study

DATE



January 14, 2008

Signature of Principal Investigator, North Carolina Study

DATE

SIGNATURE FORM

4-H Study of Positive Youth Development

YOUTH PARTICIPANT'S CONSENT:

I have read and understood the above information. I consent to participate in the described research and I give my consent to participate.

Parent Signature (if youth is 18 or over)

Date

Please PRINT Your Name

PLEASE RETURN THIS FORM TO YOUR CHILD'S STUDY SITE LEADER

(KEEP FIRST PAGE FOR YOUR RECORDS)

APPROVED

FEB 20 2009

Tufts SBER IRB

EXPIRES

JUL 14 2009

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